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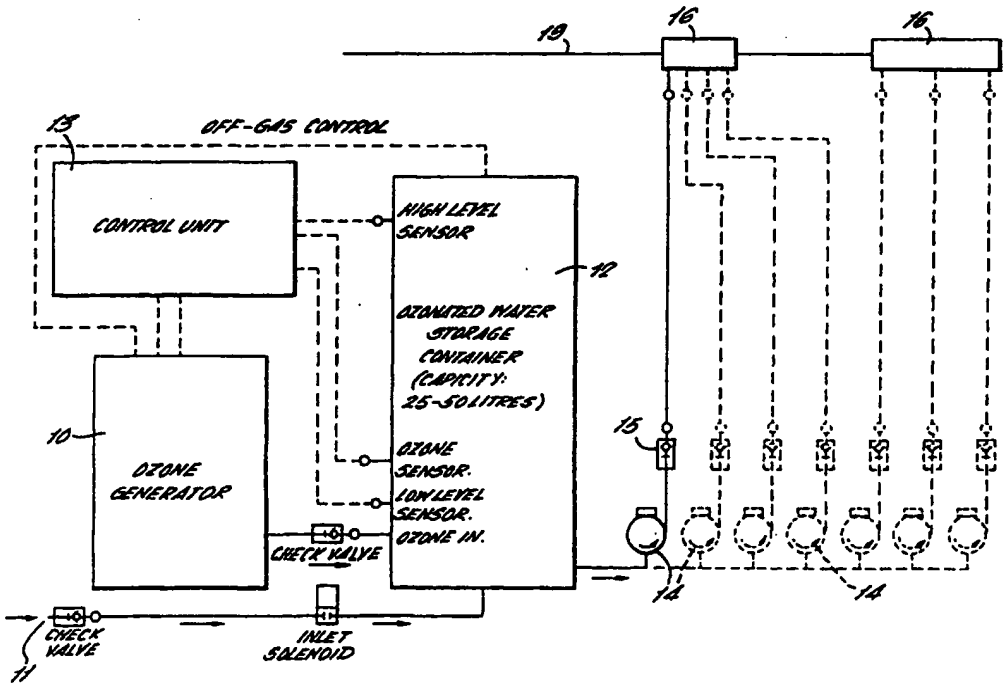
(54) Title: MEDICAL DEVICE DISINFECTION



(57) Abstract: The disclosure relates to a method of disinfecting medical theatre care equipment comprising the steps of causing ozonated water to flow over the surfaces of the equipment at a predetermined concentration and flow rate for a predetermined time and monitoring the concentration of ozone in the water leaving the equipment. The flow is terminated when the concentration of ozone leaving the equipment is substantially the same as that being delivered to the equipment.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MEDICAL DEVICE DISINFECTION

This invention relates to the disinfection of medical equipment such as endoscopes and other health care equipment such as bed pans.

Medical devices and in particular endoscopes have historically been disinfected by either heat or chemicals. Current disinfection of endoscopes is carried out by two methods; one a cold process, and the other a heated process.

i) **Cold Process**

This is normally used when the endoscopes cannot be disinfected by using heat, i.e. most flexible endoscopes. The endoscopes are manually cleaned and then put into a washer disinfector for an automatic process. This process gives the scopes a pre-wash, a wash with a disinfectant, and a final rinse with water. The disinfectant wash allows a contact time dependent on the manufacturer of the disinfectant, e.g. Cidex (Johnson and Johnson), Nu-Cidex (Johnson and Johnson), Gigasept (Schule and Mayer).

General method

Cold processing allows a batch of disinfectant to be re-used, the number of cycles dependent on the washer disinfector and the level of dilution taking place. Once this number of cycles is completed, the batch of disinfectant is dumped to waste and the machine re-charged with a fresh bash.

ii) **Hot Process**

Some endoscopes (mainly rigid ones) can be

processed in a normal sterilising autoclave at 120-130°C. For endoscopes such as flexible ones that cannot withstand this temperature, there are a range of washer disinfectors that disinfect by heating to a lower temperature of 50-55°C.

This process gives the scopes a pre-wash, a heated wash with a small amount of disinfectant, and then a final rinse with water. The heated wash takes a small amount of concentrated disinfectant, and by heating to 50-55°C causes the chemical to vaporise and thus provide the efficiency required. This process normally uses gluteraldehyde as the disinfectant, and the small amount used each time is a single use. This process tends to have longer cycle times than cold processing.

The heated process is more prevalent in Europe, while cold processing is utilised in the UK and US.

The method of the invention also provides an alternative to the use of steam.

Ozonated water is widely used to kill bacteria. However, when generating and dissolving ozone in water it is usual to expect levels of under 1 ppm. We have found that we are not able to disinfect medical devices to the required standard or within an acceptable time period using such levels of ozone concentration. Effective disinfection can only be achieved with a precise combination of flow over and through the device, ozone levels, and time.

The criteria for disinfection of the endoscopes have been developed by Dr. J Babb of the Hospital Infection Research Laboratory (HIRL) at City Hospital NHS Trust, Birmingham, as described later and is key to the validation of the process. The process fulfils the HIRL test criteria for endoscope washer disinfectors, i.e. mean $\log_{10}$ reduction >6 (99.9999%) with no individual reduction <5 (see Appendix 3). Although external validation of the process can be undertaken, it is impractical to undertake on a daily basis. Within the process we have been able to measure the ozone levels at the inlet and outlet of the process. This has allowed us to calculate how long the process needs to run to give the required disinfection. As ozone concentration is depleted on contact with bacteria, if the inlet and outlet levels are identical there is minimal bacteria remaining. As bacteria levels have to be very low to validate the unit for a predetermined time after equilibrium is reached.

Thus this invention relates to ozonated water as a substitute for the traditional chemical method of disinfection. Although the development and validation has been undertaken on endoscopes, the process and technology is relevant to many medical devices.

The invention provides a method of disinfecting medical equipment comprising the steps of causing ozonated water to flow over the surfaces of the equipment at a predetermined concentration and flow rate for a predetermined time and monitoring the concentration of ozone in the water leaving the equipment and terminating the flow when the concentration of ozone leaving the equipment is substantially the same as that being delivered to the equipment. Thus the rinse water produced does not

contain active sanitants.

The following is a description of some specific embodiments of the invention, reference being made to the accompanying drawings, in which:

Figure 1 is a schematic diagram showing the apparatus used for carrying the disinfection of medical equipment such as endoscopes; and

Figure 2 shows a number of different scopes to which the cleaning process is applicable.

Figure 1 shows a unit based around an electrochemical generator stack 10, where Hydrogen (H) and Ozone (O^3) are generated. The stack is fed by a dedicated de-ionised water supply 11 at a pressure of one bar, to maintain the integrity and efficiency of the cells and the long-term quality of the feed water. Power for the stack is supplied from a variable DC supply (not shown). There is also a battery back-up system (not shown) to support the cell in the event of a power failure.

Hydrogen gas is re-absorbed and/or catalytically converted. Ozone is supplied under pressure to a contactor 12 containing 25-50 litres of filtered water via a diffuser block. This allows the ozone gas to bubble into the water to produce a high concentration solution (typically at least 4 ppm, for example 6+ppm). The level of water in the contactor is controlled and filled through solenoid valves, the operations being initiated by a micro-processor operated control unit 13 through software instructions. Ozone concentration levels are constantly monitored to ensure correct values.

Any excess ozone off-gas is collected at the top of the contactor and passed to a destruct column, where it is processed through an absorber. When operating at full capacity the cell produces perceptible heat, and so water used in the cell for electrolysing is cooled with a heat exchanger and refrigeration plant.

To disinfect effectively an endoscope, ozonated water needs to be pumped through all the internal channels of the scope at a flow rate and concentration level sufficient to kill organisms that may remain after a manual clean has taken place. The water is supplied at ambient temperature but could be pre-heated up to 40°C to accelerate the disinfection process if required. In our testing we have found these to be concentration level of at least 4ppm, preferably about 6ppm and not more than 15ppm, and a flow rate that equates to 2.2 L/min. These parameters need to be applied for a minimum period of 10 minutes and a maximum of 15 minutes to ensure all internal channels of a normal endoscope have been disinfected.

Ozonated water is supplied from the contactor to a supply pump 14 having connectors 15 for coupling to the individual endoscope channels 16. Spent ozonated water is directed to waste via the distal end of the endoscope 19.

During testing and development a method was devised that determined whether ozone has achieved the intended uses. With a known concentration of ozonated water entering a test sample contaminated with "Pseudomonas aeruginosa NCTC 6749" of a known value, a second sensor was used to monitor the water output from the test equipment. When the exit concentration level rose to match the known input, it was assumed

that by then ozone had killed any remaining organisms. The flow of ozonated water was continued for a further 5 minutes after that equilibrium was reached. Sterile water samples were taken and cultured to established protocols and showed that the method had achieved the necessary kill rates, to be declared a process disinfectant.

Previous tests were conducted that used ozone concentrations that varied from 0.1-18ppm, and flow rates as low as 400ml/min. Contact times also varied from 5 minutes to as much as 25 minutes, but in all cases the kill rates achieved were inferior to those reached when the optimised settings previously stated were used.

KEY POINTS

* Safe operating media - chemical disinfectants are sensitising agents and are possibly tetragenic.
* Cold Process.
* One Shot Process.
* Process validated.
* Closed loop system - ozone levels monitored at discharge.
* Critical parameters of ozone concentration, flow discharge rates, and time established.
* Residue free disinfectant.

TEST METHOD

The biopsy and suction channels of an Olympus gastroscope 20 (Type GIF Q10) shown in Figure 2 were contaminated having removed the air/water and suction valves 21,22 with an overnight broth culture of *Ps.*

aeruginosa NCTC 6749 enriched with 10% horse serum. The instrument was left to drain / dry for 10 minutes at room temperature before sampling, i.e. pre-disinfection count or processing and sampling, ie. post-disinfection count. The endoscope was re-contaminated prior to each test cycle. After processing in an endoscope washer disinfector by coupling supply and return conduits to the air/water and section valve parts, the endoscope channels were sampled to detect surviving test bacteria. This was done by flushing 10 ml of sterile water through the channel lumens and collecting the washings in a sterile container at the distal tip. These were diluted and plated onto typtone soya agar plates, which were incubated at 37°C for 18 hours. The number of colony forming units of the test organism were enumerated and counts transposed to the $\log_{10}$ system. The log reduction (RF) were calculated for each cycle, i.e.:

$\log_{10}$ pre-disinfection count - $\log_{10}$ post-disinfection count = $\log_{10}$ reduction (RF)

It is normal to use a pre-disinfection count of 8 $\log_{10}$ contamination and aim for a post-disinfection count of less than 2 $\log_{10}$, giving a $\log_{10}$ reduction of 6.

Similar methods are used for colonoscopes (see Figure 3) and duadenoscopes (see Figure 4).

Definition of Disinfection

PHLS - Chemical Disinfection in Hospitals

Definitions

Disinfection: A process used to reduce the number of micro-organisms but not usually of bacterial spores; the process does not necessarily kill or remove all micro-organisms, but reduces their number of a level which is not harmful to health. The term is applicable to the treatment of inanimate objects and materials and may also be applied to the treatment of the skin, mucous membranes and other body tissues and cavities.

ENDOSCOPE TESTS

Log_{10} reductions in test bacteria from the biopsy and suction channels of two endoscopes using ozonated water for 10 minutes

Contact time	Water (control)		Ozonated water	
	Biopsy channel	Suction channel	Biopsy channel	Suction channel
Olympus GIF Q10				
Pre-treatment	8.58	8.41	8.43	8.54
Post-treatment				
Cycle 1	4.74	3.63	5.95	6.33
Cycle 2	3.70	4.46	6.04	6.39
Cycle 3	4.17	4.45	6.17	6.39
Mean log_{10} RF	**4.20**	**4.09**	**6.05**	**6.33**
Fujinon Colonoscope				
Pre-treatment	8.59	8.69	8.59	8.69
Post-treatment				
Cycle 1	5.48	5.28	5.75	5.99
Cycle 2	5.55	5.46	6.44	6.61
Mean log_{10} RF	**5.52**	**5.37**	**6.10**	**6.30**

CLAIMS

1. A method of disinfecting medical theatre care equipment comprising the steps of causing ozonated water to flow over the surfaces of the equipment at a predetermined concentration and flow rate for a predetermined time and monitoring the concentration of ozone in the water leaving the equipment and terminating the flow when the concentration of ozone leaving the equipment is substantially the same as that being delivered to the equipment.

2. A method as claimed in claim 1, wherein the equipment is subjected to a manual washing process prior to disinfection by ozonated water.

3. A method as claimed in claim 1 or claim 2, wherein the ozonated water has a concentration of at least 5 ppm and not more than 15 ppm.

4. A method as claimed in claim 3, wherein the ozonated water has a concentration of 15ppm.

5. A method as claimed in claim 3 or claim 4, wherein the flow rate of ozonated water over the surfaces of the equipment is approximately 2.2 litres per minute.

6. A method as claimed in any of the preceding claims, wherein the equipment has an internal channel or channels, wherein ozonated water is delivered over the outer surfaces of the equipment and through the internal channels of the equipment.

7. A method as claimed in any of the proceeding claims when the equipment is an endoscope having one

or more internal channels through which said ozonated water is caused to flow.

8. A method as claimed in any of the preceding claims, wherein the equipment is subjected to a final rinse in water following said disinfecting process.

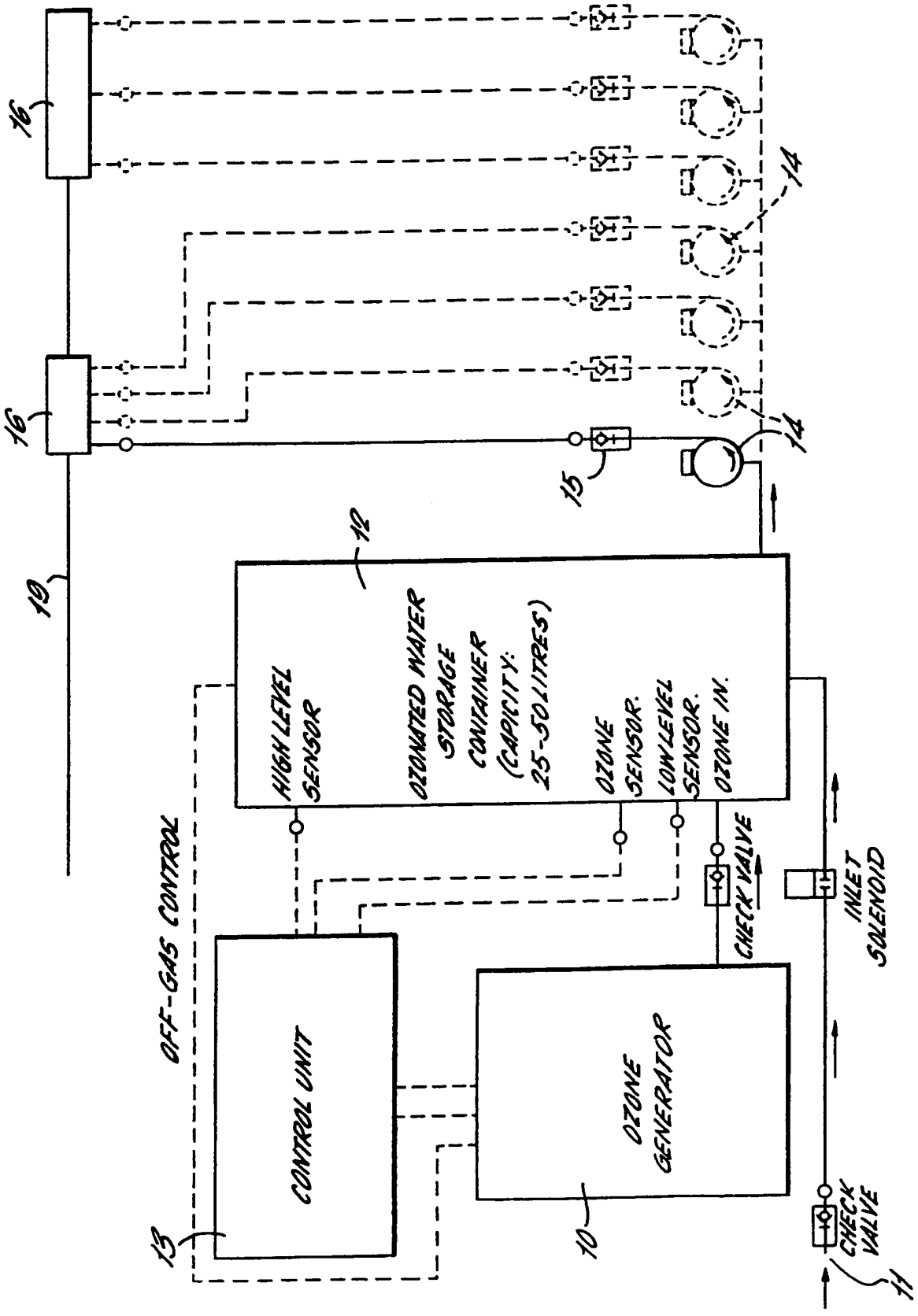
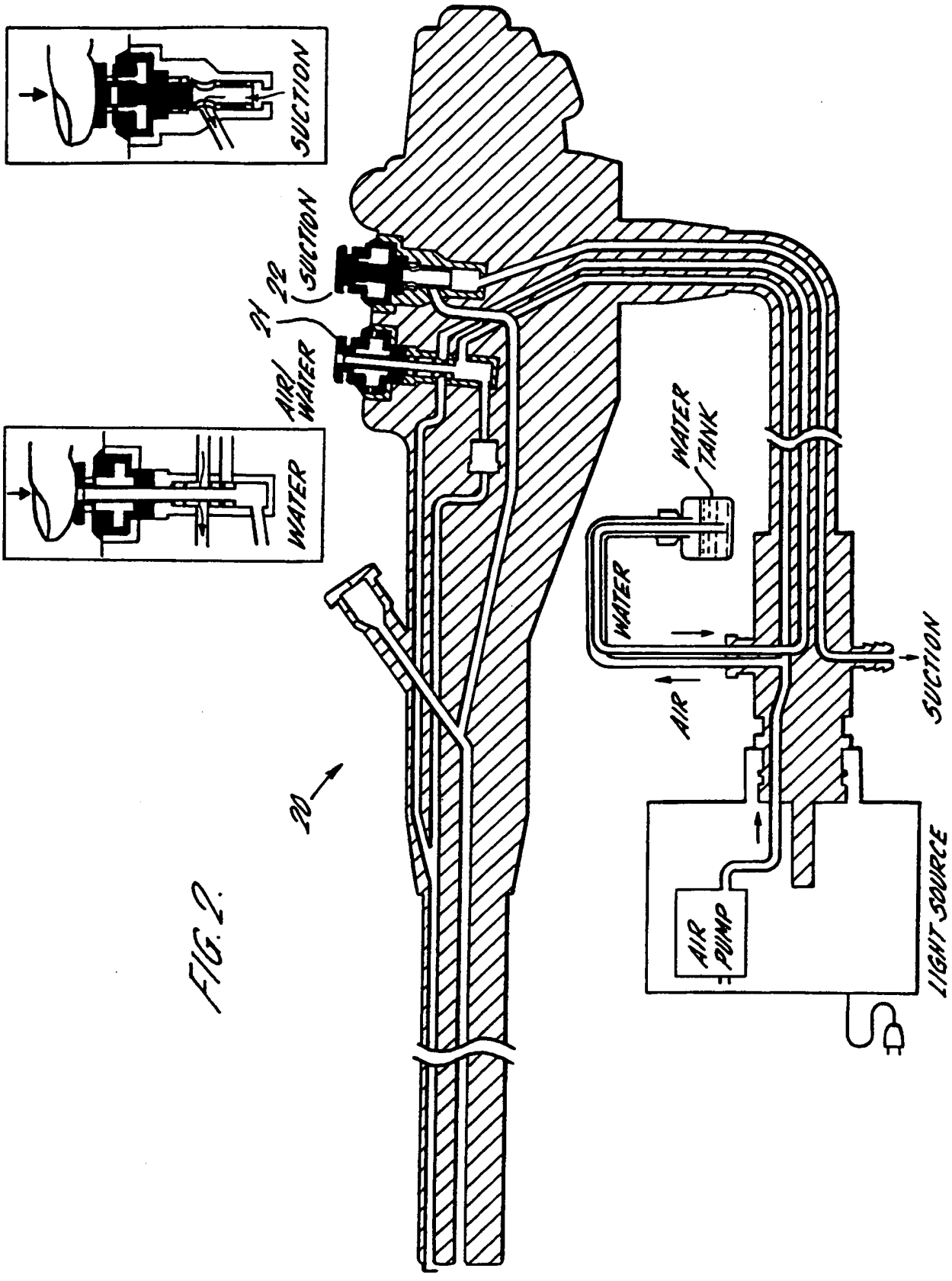

16
16
14
14
15
19
12
HIGH LEVEL SENSOR
OZONATED WATER STORAGE CONTAINER (CAPACITY: 25-50 LITRES)
OZONE SENSOR.
LOW LEVEL SENSOR.
OZONE IN.
OFF-GAS CONTROL
CHECK VALVE
INLET SOLENOID
CONTROL UNIT
OZONE GENERATOR
13
10
CHECK VALVE
11

FIG. 1.


SUCTION
SUCTION
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21
AIR/WATER
WATER
WATER TANK
WATER
AIR
SUCTION
20
AIR PUMP
LIGHT SOURCE

FIG. 2.

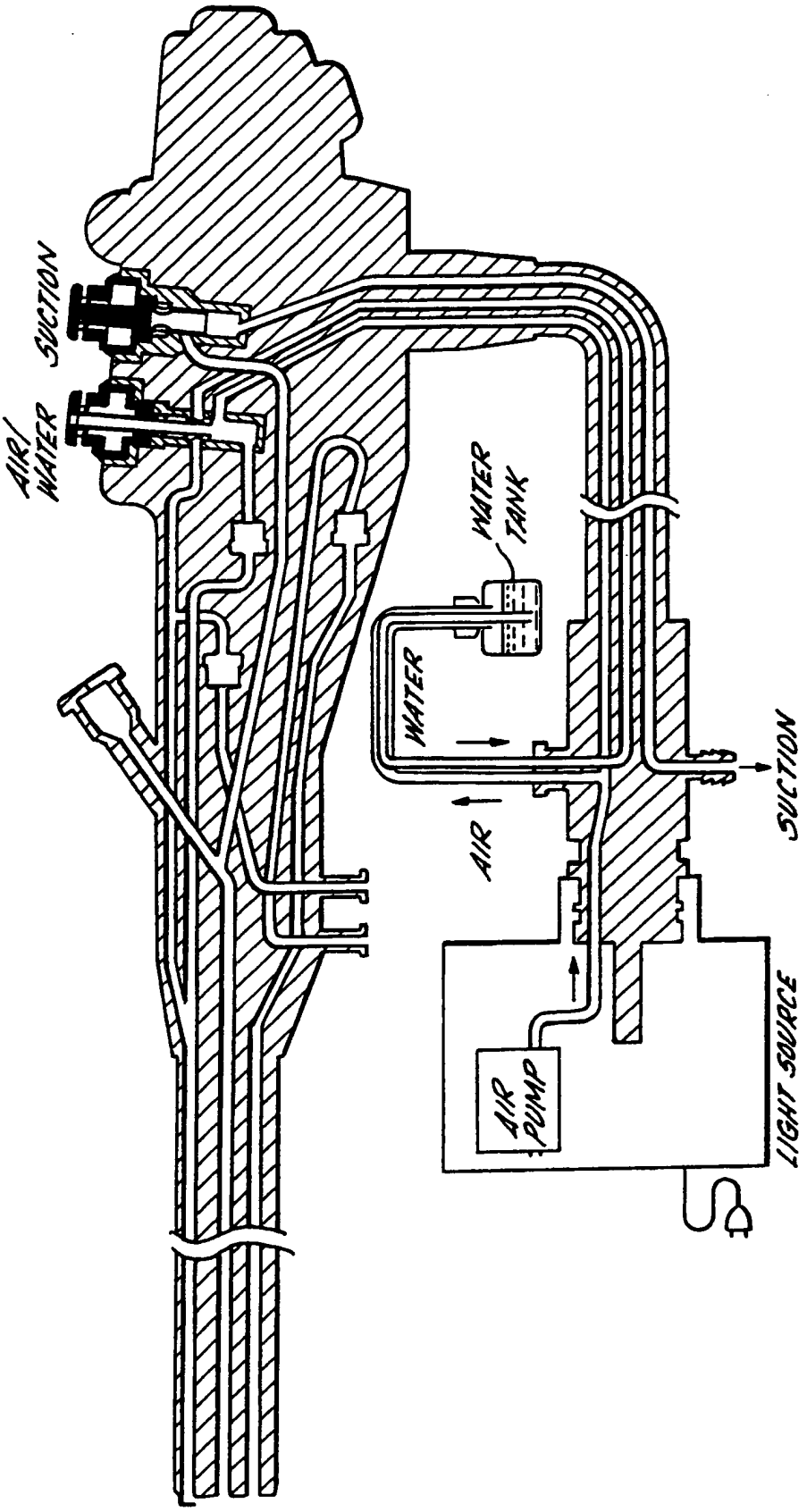
AIR/
WATER
SUCTION
WATER
TANK
WATER
AIR
SUCTION
AIR
PUMP
LIGHT SOURCE

FIG. 3.

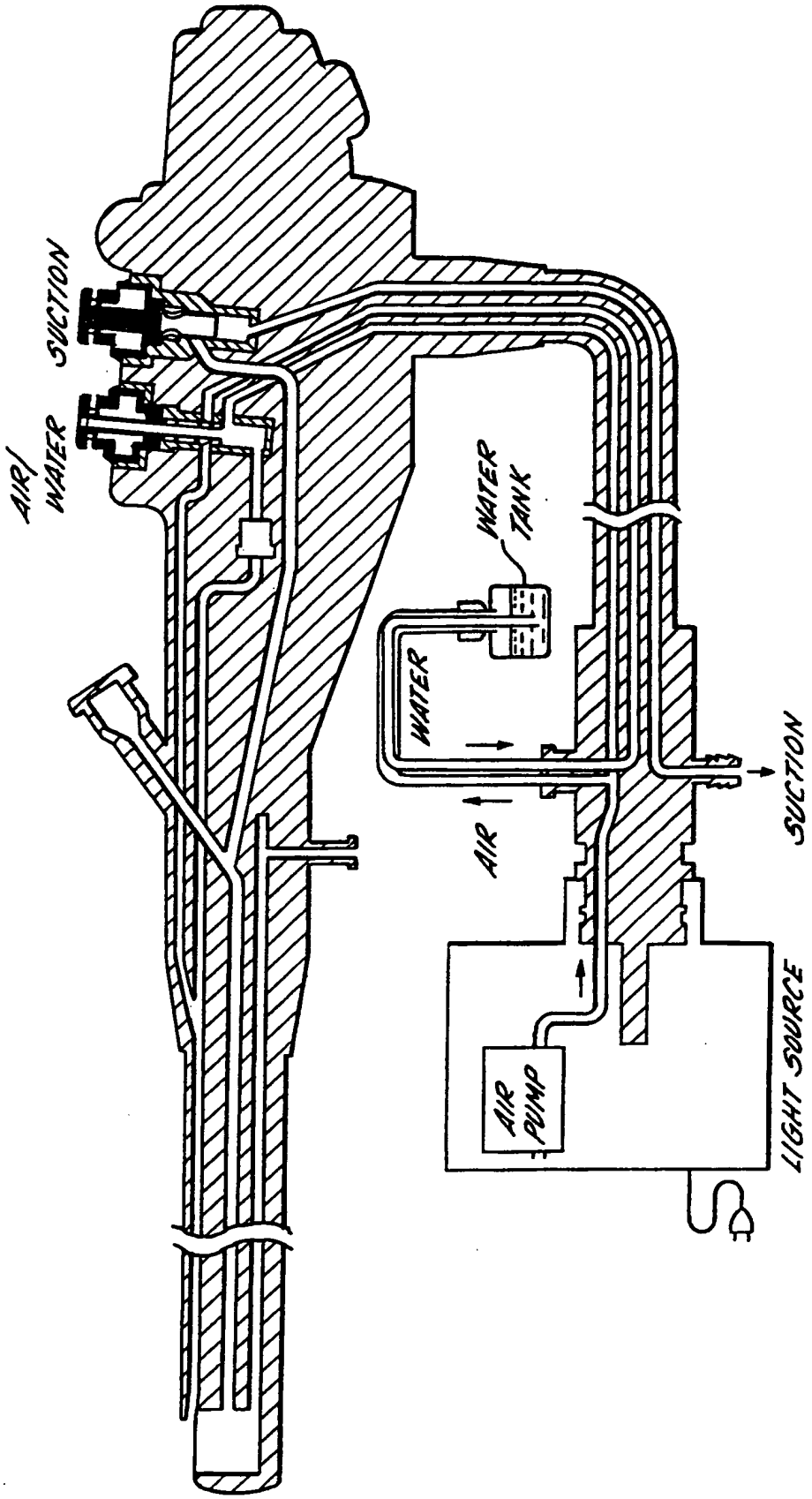
AIR/ WATER
SUCTION
WATER TANK
WATER
AIR
SUCTION
AIR PUMP
LIGHT SOURCE

FIG. 4.

INTERNATIONAL SEARCH REPORT

Inte. ional Application No
PCT/GB 01/00568

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L2/20 A61L2/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 443 801 A (LANGFORD TERRENCE R) 22 August 1995 (1995-08-22) claims ---	1,2,6-8
X	US 5 520 893 A (KASTING JR JOHN R ET AL) 28 May 1996 (1996-05-28) claims ---	1
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A	US 5 853 014 A (ROSENAUER CHARLES E) 29 December 1998 (1998-12-29) claims; figures --- -/--	1-8

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
25 June 2001	05/07/2001

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Inte. ional Application No
PCT/GB 01/00568

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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